UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, *ex rel.* JAMES ALLEN,	)	
Plaintiffs,	)	
v.	)	Civil No. 11-22 (DWF/AJB)
GUIDANT LLC, formerly doing business as GUIDANT CORPORATION, GUIDANT SALES LLC, formerly doing business as GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., and BOSTON SCIENTIFIC CORPORATION	)	**Demand for Jury Trial**
Defendants.	)	

UNITED STATES' COMPLAINT

The United States brings this action under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*. and the common law to recover losses from false claims that defendants Boston Scientific Corporation, Guidant LLC, Guidant Sales LLC, and Cardiac Pacemakers, Inc. (collectively "Guidant" or the "Company") caused to be submitted by health care providers to the Medicare program.

Guidant knew as early as April 2002 that an implantable cardiac device it manufactured and sold, known as the Prizm 2, contained a potentially life-threatening defect. Yet, even after the Company took corrective manufacturing action to remedy the defect and even though devices without a known defect were available, the Company continued to sell the defective versions of the devices. Similarly, Guidant knew as early as November 2003 that an implantable cardiac device it manufactured and sold, known as the Renewal,

contained a similar, potentially life-threatening defect. Yet, even after the Company took corrective manufacturing action to remedy the defect and even though devices without a known defect were available, the Company continued to sell the defective versions of the devices. Both times, Guidant failed to tell physicians, patients, the Food and Drug Administration ("FDA"), and even its own sales force about the problems, and Guidant eventually pled guilty to misleading the FDA about its actions in connection with the Prizm and the Renewal.

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law theory of unjust enrichment.

2. The United States bases its FCA claims on Guidant causing the submission of false or fraudulent claims to the Medicare program in violation of 31 U.S.C. § 3729(a)(1).

3. Generally, no payments may be made under Medicare for expenses incurred for items and services that are not "reasonable and necessary" for the diagnosis and treatment of an illness. 42 U.S.C. § 1395y(a)(1)(A).

4. In 2002 and 2003, respectively, Guidant learned that two types of implantable cardiac devices that it manufactured and sold, the Ventak Prizm 2 DR and the Contak Renewal 1 and 2, had the potential to "arc," which would lead the device to fail to deliver a necessary, and often potentially life-saving, shock to the patient with the implanted device.

5. Guidant implemented corrective manufacturing actions for the Prizm 2 and the Renewal in order to prevent arcing in those devices.

6. At the time it learned of the arcing defects and at the time of the corrective manufacturing actions, Guidant did not take appropriate action to disclose the arcing defects or the corrective manufacturing actions to the FDA or health care providers.

7. After Guidant learned of the arcing defects and after it implemented corrective manufacturing actions, Guidant continued to sell defective versions of the Prizm 2 and the Renewal devices that had been manufactured prior to the corrective actions.

8. Guidant also failed to reveal the arcing defect to health care providers who may have had defective versions of the Prizm 2 or Renewal on hand and that had not yet been implanted into patients.

9. At all times when comparable devices without an arcing defect were available, it was not reasonable and necessary for the devices with the arcing defect to be implanted in patients.

10. It was reasonably foreseeable that the defective versions of the Prizm 2 and the Renewal devices would be implanted into Medicare patients.

11. As the direct, proximate, and foreseeable result of Guidant's course of conduct, as set forth above and herein, Guidant knowingly caused approximately 2,000 false or fraudulent claims to be submitted to the Medicare program for the implantation of defective Prizm 2 and Renewal devices.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

13. This Court may exercise personal jurisdiction over Guidant LLC, formerly doing business as Guidant Corporation, pursuant to 31 U.S.C. § 3732(a) and because Guidant LLC transacts business in the District of Minnesota.

14. This Court may exercise personal jurisdiction over Cardiac Pacemakers, Inc. pursuant to 31 U.S.C. § 3732(a) and because Cardiac Pacemakers, Inc. transacts business in the District of Minnesota. Cardiac Pacemakers, Inc. is a Minnesota corporation with its principal place of business in Minnesota.

15. This Court may exercise personal jurisdiction over Guidant Sales LLC, formerly doing business as Guidant Sales Corporation, pursuant to 31 U.S.C. § 3732(a) and because Guidant Sales LLC transacts business in the District of Minnesota.

16. This Court may exercise personal jurisdiction over Boston Scientific Corporation pursuant to 31 U.S.C. § 3732(a) and because Boston Scientific Corporation transacts business in the District of Minnesota.

17. Venue is proper in the District of Minnesota under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because all defendants reside in and/or transact business in this District.

III. PARTIES

18. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program.

19. James Allen is an individual residing in Lancaster, New York. He commenced an action on July 10, 2008 under the *qui tam* provisions of the FCA, which enable a private person to bring an action in the name of the government. Mr. Allen filed a First Amended Complaint on July 22, 2010.

20. Defendant Guidant Corporation was an Indiana corporation, with its principal place of business at 11711 N. Meridian Street, Suite 850, Carmel, IN 46032. Guidant Corp.'s Cardiac Rhythm Management (CRM) Division is the division that, upon information and belief, at all times relevant to this Complaint, developed, researched, advertised, promoted, marketed, and sold all of Guidant's implantable cardioverter defibrillators ("ICDs"), including the Prizm 2 and Renewal. Upon information and belief, at all times relevant to this Complaint, the CRM Division's operations were principally conducted out of its facilities at 4100 Hamline Ave. North, St. Paul, MN 55126.

21. During the relevant time period, Guidant was organized as a corporation and did business under the name "Guidant Corporation." On or about February 19, 2010, Guidant Corp. filed articles of conversion with the Indiana Secretary of State to convert its corporate form to a limited liability company, with the name "Guidant LLC."

22. Guidant LLC is a wholly-owned subsidiary of Boston Scientific Corporation.

23. Guidant LLC was convicted of two misdemeanors in this District for violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(q)(2) and 331(q)(1)(B), for its conduct relating to the Prizm 2 and the Renewal and to certain of the allegations herein.

24. At all times relevant to this Complaint, Guidant Corp. (now Guidant LLC) sold the Prizm 2 and Renewal devices through its wholly-owned subsidiary, defendant Guidant Sales Corporation. On July 30, 2010, Guidant Sales Corporation filed articles of conversion with the Indiana Secretary of State to become a limited liability company, with the new name "Guidant Sales LLC." Guidant Sales LLC has its principal place of business at 4100 Hamline Ave. North, St. Paul, MN 55112.

25. Defendant Cardiac Pacemakers, Inc. is, upon information and belief, a Minnesota corporation with its principal place of business at 4100 Hamline Ave. North, St. Paul, MN 55112. Upon information and belief, Cardiac Pacemakers, Inc. is a wholly-owned subsidiary of Guidant Corporation (now Guidant LLC), and was so at all times relevant to this action. Cardiac Pacemakers, Inc. was responsible for certain submissions to the FDA for the devices at issue in this matter, including a submission that Guidant LLC has admitted was false and misleading.

26. Defendant Boston Scientific Corporation describes itself as a worldwide developer, manufacturer, and marketer of medical devices. Boston Scientific is incorporated in the State of Delaware, with its principal executive office located in Natick, Massachusetts. In 2006, Boston Scientific acquired Guidant Corporation (now Guidant LLC) and its subsidiaries through a stock purchase agreement in which Guidant Corporation shareholders

exchanged their shares for shares of Boston Scientific and cash. Guidant's assets, liabilities, and operations have been relocated to other Boston Scientific entities, with Guidant LLC continuing to operate and to retain post-retirement benefit obligations, international tender obligations, inter-company financial activities, and certain third-party contracts. Since the transaction, Boston Scientific has operated as a successor of Guidant Corporation. The successor generation of products manufactured and sold by Guidant Corporation, including the devices at issue in this matter, are now manufactured and sold by Boston Scientific. In addition, the sales force previously employed by Guidant Corporation to sell ICDs is now employed by Boston Scientific in the same or similar capacity.

IV. THE LAW

A. The False Claims Act

27. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1) (2006).

28. The FCA provides, in pertinent part, that any person who:

> (a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person[.]
>
> * * *

> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information
>
> (1) has actual knowledge of the information;
>
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (3) acts in reckless disregard of the truth or falsity of the information, and
>
> no proof of specific intent to defraud is required.

31 U.S.C. § 3729.[1]

29. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

B. The Food, Drug, and Cosmetic Act and Related Regulations

30. Implantable cardioverter defibrillators (ICDs) are classified as Class III medical devices under the federal Food, Drug, and Cosmetic Act ("FDCA") because they are used for "supporting or sustaining human life" and are "of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C)(ii)(I). Class III devices require pre-market approval from the FDA before they can be sold in the United States.

31. To obtain pre-market approval, a manufacturer must submit a pre-market approval application ("PMA") to the FDA. 21 U.S.C. § 360e(c)(1). FDA regulations require

[1] On May 20, 2009, the Fraud Enforcement and Recovery Act of 2009 (FERA) became law. Pub. L. No. 111-21, 123 Stat. 1617 (2009). Section four of FERA revised certain provisions of the False Claims Act, including Section 3729(a)(1), but the amendment to that section is not retroactive.

that, after approval of a PMA, an applicant must "submit a PMA supplement for review and approval by the FDA before making a change affecting the safety or effectiveness of the devices for which the applicant has an approved PMA[.]" 21 C.F.R. § 814.39(a). According to the regulations, "changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: . . . (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." *Id.*

32. The FDCA and FDA regulations require submission of a written report to the FDA within ten working days of initiating any "correction" of a device implemented to reduce a "risk to health" posed by the device. 21 U.S.C. § 360i(g); 21 C.F.R. § 806.10.

33. "*Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d).

34. "*Risk to health* means (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. § 806.2(j).

35. The removal or correction of a device that the agency considers to be in violation of the FDCA and against which the agency would initiate legal action is called a "recall." 21 C.F.R. § 7.3(g).

C. The Federal Medicare Program

36. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, which is part of the Department of Health and Human Services. At all times relevant to this Complaint, CMS contracted with private contractors referred to as "fiscal intermediaries" and "carriers" to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

37. For inpatient treatment, reimbursement to treating facilities (such as hospitals) is governed by Medicare Part A, 42 U.S.C. §§ 1395c-1395i-5. For outpatient treatment, reimbursement to health care providers (such as doctors) is governed by Medicare Part B, 42 U.S.C. §§ 1395j-1395w-4.

38. To obtain Medicare reimbursement, providers submit claims using forms (known as CMS 1500s for outpatient claims and UB-92 or UB-04 for inpatient treatment). Providers identify by code on the appropriate form, among other things, the principal diagnosis of the patient and the procedures and services rendered.

39. Under the Medicare program, "no payment may be made under part A or part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

V. IMPLANTABLE CARDIOVERTER DEFIBRILLATORS ("ICDs")

40. This case involves two lines of implantable cardiac devices manufactured by Guidant: the Ventak Prizm 2 DR (the "Prizm 2") and the Contak Renewal 1 and 2 (the "Renewal"). Both products are defibrillators, which are designed to prevent sudden cardiac death by detecting and treating ventricular tachycardia and ventricular fibrillation. If the devices detect tachycardia or fibrillation, they emit an electrical pulse to deliver a potentially life-saving "shock" to the heart to return it back to normal rhythm.

41. More specifically, an ICD is an implantable medical device that is used to correct heart arrhythmia (abnormal heart rhythm). The device is surgically implanted in the patient's chest cavity and connected to the patient's heart by electrical wires called "leads." The "header" of the device is a formed plastic cap that channels wires from the device's metallic pulse generator, which contains the battery, to a port where the wires are connected to the leads. The "feedthrough wire," located within the header, is designed to carry the electrical charge from the pulse generator to the leads. Implantable cardiac resynchronization therapy defibrillators ("CRT-Ds") are ICDs with an additional function that enables the heart to pump more efficiently.

42. "Interrogation" describes the evaluation of an ICD and the retrieval of stored information from the device. An interrogation assesses various factors that could affect the performance of the ICD, such as whether the leads or pulse generator are functioning normally, the status of the battery, and whether an abnormal heart rhythm has been detected by the ICD.

43. Patients who are treated with ICDs include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat), or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death, unless the device delivers the proper therapy to put the patient's heart back into a normal cardiac rhythm.

44. Once implanted, a properly functioning ICD or CRT-D continuously monitors the patient's heartbeat for irregular rhythms. If tachycardia is detected, the device will generate a series of timed, electrical pulses delivered to the heart along the leads to reset the heart to normal rhythm. Similarly, when ventricular fibrillation is detected, the device will deliver sudden shocks along the leads to the heart to stop the potentially-fatal heart quivering.

45. In 2002 and 2003, respectively, Guidant discovered that the Prizm 2 and Renewal devices suffered from an electrical defect known as "arcing." Arcing occurs when the device detects the irregular heartbeat and delivers a shock, but instead of the current going to the lead and then the heart, the current "arcs" back to the device itself. This causes the device to divert energy away from the leads in a short circuit, rendering the device ineffective to deliver therapy. A failure to deliver the potentially life-saving shock to the patient can result in death.

46. In August 2000, the FDA approved Guidant's application for the Ventak Prizm 2 DR Model 1861 ("Prizm 2"). In its notification to Guidant that the device had been approved, FDA reminded the Company of the requirement that "[b]efore making any change

affecting the safety or effectiveness of the device, [Guidant must] submit a PMA supplement for review and approval by FDA[.]" The FDA further specified to Guidant in the approval for the Prizm 2 that "[a] PMA supplement . . . be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

47. Guidant first offered the Prizm 2 for sale in the United States in or about 2000.

48. In 2002, the FDA approved Guidant's application for the Contak Renewal 1 Model H135 ("Renewal"). In its notification to Guidant that the device had been approved, FDA reminded the Company of the requirement that "[b]efore making any change affecting the safety or effectiveness of the device, [Guidant must] submit a PMA supplement for review and approval by FDA[.]" The FDA also required that "[a] PMA supplement . . . be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

49. Guidant first offered the Renewal for sale in the United States in or about 2002.

VI. THE PRIZM 2

50. In or about February 2002, a physician observed that a Prizm 2 implanted in one of his patients had malfunctioned, leaving the doctor unable to interrogate the device. The device was subsequently surgically removed from the patient or "explanted," and shipped to Guidant, which sent the device to its Reliability Lab for analysis.

51. Guidant opened a tracking report, called a Field Discrepancy Notification report ("FDN"), in late February 2002. According to the FDN, Guidant's lab technician concluded that a short between the feedthrough wire and the backfill tube (connected to the device case) inside the header was the cause of a high current condition, *i.e.*, arcing. The arcing depleted the battery, resulting in the inability of the physician to interrogate the device and rendering the device unable to deliver a shock if needed. The Guidant technician further noted that the insulation of the feedthrough tubing "appear[ed] to have a hole in it[.]"

52. In March 2002, another physician reported to Guidant his observation of a malfunctioning implanted Prizm 2. The device was explanted and shipped to Guidant for analysis.

53. In the FDN for this second event, the Guidant lab technician noted that when the "[d]evice was charged up to approximately 570 volts, a loud spark and loud snap was produced from the header. Visual of the header found the DF negative wire is melted against the backfill tube." The technician concluded that "corrective action is required . . . to ensure the feedthru wire cannot short against the stem."

54. The arcing in Guidant's Prizm 2 devices was caused by a breakdown in the polyimide insulation in a feedthrough wire. When the wire, carrying a negatively charged current, was positioned too close to the positively charged backfill tube, the current would arc from the wire to the tube, causing the device to divert energy away from the leads in a short circuit, rendering the device ineffective to deliver therapy.

55. Guidant itself termed the arcing a "failure mode" for the device.

56. Guidant believed that this "failure mode" would continue to recur unless the design of the device was changed.

57. On April 16, 2002, to modify the devices, Guidant implemented Engineering Change Order ("ECO") 40773, a manufacturing corrective action Guidant took to prevent arcing. The change order called for additional medical adhesive coating to be added to the backfill tube to act as further insulation that would also prevent the feedthrough wire from coming too close to the backfill tube.

58. The change order was intended to affect both the safety and efficacy of the Prizm 2. It was implemented for the purpose of correcting a defect that could leave the device inoperable.

59. Guidant believed that this manufacturing change "completely corrected the [arcing] situation" that was causing failures in the Prizm 2, according to an internal Guidant report dated January 30, 2003.

60. Nonetheless, Guidant did not submit a PMA supplement to the FDA before making this manufacturing corrective action.

61. On August 16, 2002, Guidant submitted to the FDA an Annual Report for the PMA for the Ventak family devices, including the Prizm 2, for the period from June 1, 2001 to May 31, 2002. The report was submitted by Guidant Corp. and Cardiac Pacemakers, Inc. Annual reports to the FDA are required to include changes to devices that do not require a supplemental PMA because the changes do not affect the safety or effectiveness of the device. 21 C.F.R. § 814.39(b). The August 2002 annual report did not disclose the April 16,

2002, corrective action the Company had implemented, nor did it describe the arcing failure mode.

62. On or about November 13, 2002, Guidant implemented a second engineering change order for the Prizm 2 designed to address the arcing failure mode.

63. Guidant regarded the November 2002 change order as, in the words of the former CRM president, a "belt and suspenders" effort to address the arcing failure mode.

64. Guidant did not submit a PMA supplement to the FDA before making the November 2002 change.

65. The next Annual Report for the devices, submitted August 19, 2003, also did not disclose the April 2002 manufacturing corrective action. Although it did refer to the manufacturing change the Company had undertaken in November 2002 to the Prizm 2, Guidant characterized that manufacturing corrective action as a "minor manufacturing change[] [that did] not affect the safety or effectiveness of the device." It further stated that "device performance is unaffected by this change . . . ." The report was submitted by Guidant Corp. and Cardiac Pacemakers, Inc.

66. Guidant LLC has since acknowledged that the description of the manufacturing changes in the 2003 Annual Report were false and misleading and has been convicted of a violation of the FDCA, 21 U.S.C. §§ 331(q)(2) (prohibiting the submission of any required report to the FDA that is false or misleading in any material respect) in relation to the 2003 Annual Report.

A. Guidant Continued To Sell Defective Devices That It Expected Would Fail

67. After the implementation of the April 2002 Change Order, there were two distinct Prizm 2 device populations being implanted by physicians into patients: (1) devices with the arcing defect that had been manufactured before the April 2002 Change Order and (2) devices manufactured after that manufacturing corrective action.

68. Guidant expected that the defective device population would continue to experience arcing events that would potentially put patients' lives at risk. In contrast, Guidant did not anticipate any arcing events in the post-Change Order device population.

69. On May 20, 2002, in order to track future arcing events internally, Guidant opened Trend Report TR 02019, titled "Feedthrough Wire to Backfill Tube Short." The trend report distinguished between devices made before the corrective action and those made afterwards. Guidant anticipated that the former population of devices likely would continue to experience arcing but the latter population would not.

70. In a June 2002 Health Risk Assessment ("HRA") that Guidant performed for the Prizm 2 arcing defect, Guidant concluded that injury to a patient stemming from an arcing event would be "life-threatening" because "unanticipated deaths *could reasonably be expected to occur*[.]" (emphasis added). The HRA further concluded that there were *no* mitigation factors for this risk and that the risk affected the *entire* pre-fix Prizm 2 patient population. Guidant did not disclose this assessment to physicians or to the FDA.

71. In 2002 and early 2003, Guidant continued to receive reports from the field about arcing in devices made prior to April 2002.

72. Nonetheless, Guidant closed Trend Report TR 02019 in April 2003 because those failures were consistent with what the Company expected would happen—that some devices manufactured before the corrective action would experience arcing and fail.

73. In closing the Trend Report TR 02019, Guidant established criteria for determining when to reopen it: namely, the report of either *four* arcing events in a 12-month period among the defective devices or *a single* arcing event from the fixed device population.

74. In fact, more than the four arcing events did occur in the defective device population. A March 2004 Tachy Field Performance Monitoring Review states that no fewer than *eight* arcing events were reported for the Prizm 2 in the preceding 12 months.

75. Nonetheless, Guidant did not reopen TR 02019 because "[a]ll events were pre-corrective action," the failures did not occur in any devices made after the manufacturing change, and the failures were consistent with what the company expected to happen in the defective device population.

76. After the Change Order was implemented in April 2002, there were still many devices that had been manufactured before April 2002 on shelves as inventory in health care facilities such as hospitals, or in stock held by Guidant sales representatives responsible for distributing and selling the devices.

77. Guidant continued to sell its existing stock of defective devices after the implementation of the April 2002 Change Order.

78. Instead of alerting physicians, patients, or even its own sales force about the arcing issue, asking for the return of devices made before April 2002 or issuing a recall, Guidant did nothing.

79. As a result, nearly 4,000 devices manufactured before April 2002 that had the arcing defect and the attendant potential to fail to deliver a life-sustaining shock were implanted by physicians into patients in the United States after April 2002, when neither the physicians nor the patients knew about the defect or the risks. Approximately 1,800 of these implants were in Medicare patients.

80. The implantation of Prizm 2 devices with the arcing defect when non-defective devices were available was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

81. From 2002 until 2005, the Company learned of at least 26 separate arcing events that had occurred in patients that had Prizm 2 devices that had been manufactured prior to the corrective action.

82. One of these failure events occurred in March 2005 in the defective device implanted in a 21-year-old patient, J.O., who died of cardiac arrest after his Prizm 2 failed to deliver the shock he needed to return his heart rhythm to normal and to save his life.

83. In total, out of about 27,000 pre-fix Prizms sold that had the potential to arc, there are at least 39 confirmed arcing events and four patient deaths potentially attributable

to Prizm arcing. In bench testing of explanted devices, Guidant observed that at least 19 additional Prizm 2 devices experienced arcing that rendered the devices inoperable.

B. The Renewal Devices

84. Between November 2003 and July 2004, Guidant learned of four separate arcing events that took place in Renewal devices implanted in patients. One such event resulted in the failure of a device to deliver potentially life-saving therapy to a patient who died after suffering a cardiac arrest.

85. The first reported arcing event occurred on November 18, 2003, after a physician observed that his patient's device presented low shocking impedance (i.e. current) on the leads upon interrogation. The device was explanted on November 19, 2003, and returned to Guidant for analysis.

86. The second arcing event occurred on May 7, 2004.

87. On or about July 28, 2004, Guidant implemented a manufacturing corrective action to address the propensity of the Renewal to arc. As with the Prizm 2, the design change, accomplished through ECO 53528, called for extra medical adhesive to be added between the pulse generator and the wires to provide additional insulation at the site where the arcing had been observed.

88. At that time, Guidant did not disclose the manufacturing corrective action of the Renewal to the FDA.

89. Through the summer of 2004, Guidant anticipated that more failures would occur within the defective device population and the Company continued to monitor and discuss the arcing problem in the Renewal.

90. On or about August 25, 2004, the Renewal arcing issue was presented to Guidant's Product Performance Committee ("PPC"), a committee responsible for "prioritizing, approving, and monitoring corrective actions for product performance[.]" Later that day, the PPC presented the issue to Guidant's Product Evaluation Committee ("PEC"). The PEC is a committee charged with "provid[ing] an independent review of significant patient health and safety issues (realized or potential) associated with [a] fielded product."

91. That same day, August 25, 2004, the PEC recommended that the Company stop shipment of all Renewals. The recommendation was based on "the severity of the [Renewal arcing] issue."

92. The PEC did not at that time recommend that the company communicate with physicians or sales representatives in order to retrieve devices or stop implants of devices that had already been sent to the field or sold to customers.

93. The following day, August 26, 2004, based on the PEC recommendation, Guidant implemented "stop ship" and "stop build" orders to cease the manufacture and shipment of Renewals from Guidant's factory. The orders did not apply to Renewals that had previously shipped out from the factory and that Guidant sales representatives still had in their possession.

94. During a September 7, 2004, meeting of the PPC, committee members discussed a 1992 article concerning a study that concluded that polyimide—the material that Guidant had used to insulate the wires in the Renewal and Prizm 2—tends to deteriorate in moist and warm conditions. The article had been identified several days earlier by a Guidant laboratory engineer.

95. By mid-September, the Company concluded that the polyimide insulation was, indeed, the root cause of the arcing problem it was seeing in the Renewal.

96. On September 28, 2004, the PPC met again and recommended that the Company continue to sell field inventory, including trunk stock (*i.e.*, defective devices manufactured before the "stop ship" order that had been previously distributed to sales representatives for sale).

97. This recommendation was elevated to Guidant's Officer Escalation Group ("OEG"). The OEG was a committee consisting of senior staff, including vice presidents and the general counsel, and was responsible for reviewing items elevated to it from the PPC, in particular, "[i]ssues that may require a Safety Alert or broad physician communication due to a customer satisfaction issue."

98. The OEG approved the PPC's recommendation to continue to sell field inventory.

99. In the following months, as the Company expected, Guidant continued to receive reports of arcing events occurring in Renewals that had been made before the manufacturing corrective action.

100. In September 2004, Guidant conducted an internal test of Prizm I devices, which also contained polyimide. Of the ten Prizm I devices Guidant tested, all ten of them exhibited "cracking" in the device's polyimide tubing. A similar test of Renewal devices showed that at least two out of the five devices experienced "cracking" in the polyimide insulation, and a third device was found to be "questionable."

101. On November 19, 2004, Guidant submitted a "Real Time Review Request" to the FDA for a redesigned header, in which it told the agency that the design change was a "manufacturing change to improve process throughput" and specifically said that the change was "not being done to correct device flaws that threaten patient safety." In fact, however, Guidant made the change in order to correct the arcing problem. Moreover, the Real Time Review request did not mention the now-known cause of the arcing, the projected rate of failure, or that Guidant had ordered the factory to stop building and shipping the devices.

102. Guidant learned of a tenth confirmed Renewal arcing event in January 2005.

103. At a January 5, 2005, special meeting of the PPC, the committee tasked Ren Russie, Director of Product Performance Reporting and Quality Assurance, and Dan Tich, Manager of Product Performance Communications, with evaluating possible physician communications concerning the arcing defect in the Renewal and presenting a recommendation as to which communication the company should issue.

104. In an email to the members of the PPC dated January 5, 2005, Russie identified six "[c]ommunication [p]ossibilities" for the Company to consider, including recalling the

device. In the email, Russie recommended either a product update or a safety advisory, both of which would include "specific background" about the Renewal.

105. The next day, Russie distributed a draft physician communication to the PPC committee. The draft described the arcing defect and anticipated that by the time the communication was sent, Guidant would already have "removed all non-implanted RENEWAL and RENEWAL 2 CRT-Ds from hospital shelves and Guidant inventory."

106. Minutes from a January 7, 2005, meeting of the PPC state that the committee, among other things: (1) "agreed to recommend to OEG that communication [to physicians] was appropriate" and (2) "agreed to recommend to OEG that remaining shelf devices should be pulled." Following the meeting, a "Dear Doctor" letter was drafted that laid out what Guidant understood about the arcing problem and how it presented. Additionally, a presentation for the FDA was drafted that, had it been submitted to the FDA, would have disclosed the arcing problem and acknowledged that "unanticipated deaths could reasonably be expected to occur."

107. Rather than taking clear, robust action to alert the FDA, physicians, and patients about the arcing issue and to prevent future implants of the defective devices, Guidant instead developed a plan designed to attract the least amount of attention possible.

108. On the afternoon of January 7, 2005, Dr. Joseph Smith, a CRM Chief Medical Officer, suggested that, rather than the approach in the draft communication from Russie, the physician communication focus instead on the "yellow screen." This refers to a yellow computer screen that was designed to appear as a physician interrogated an implanted device

at a routine patient visit and a problem was detected in the leads of the device. The warning said that "A LOW shocking lead impedance has been recorded. Please evaluate lead integrity." The warning did not refer to any potential malfunction with the pulse generator, the ICD itself, or to arcing in particular, although by that time Guidant knew that this yellow screen mentioning only the leads was what appeared if the device had arced.

109. In an email sent that same day, Russie expressed reservations with the approach that Smith had proposed. Russie stated that "[t]his would lead to virtually zero explants." He noted the approach "falls short" in that it "[d]oesn't provide a mechanism to remove product from the field" and "will seem wholly inadequate in the future if the failure rate becomes high."

110. In a January 10, 2005, meeting, the OEG considered a PPC recommendation that Guidant "[r]emove (recall) remaining pre-corrective action product from distribution because it now appears to perform worse than Prizm 1[.]" On information and belief, the OEG rejected the PPC's recommendation.

111. The PPC met again later that day. One Guidant employee memorialized the discussion at the meeting in his notebook: "Can we go get devices? . . . . Would prefer generic letter. . . . . *Can we do this quietly without focusing on R1/R2 [Renewal 1 and 2]?*" (emphasis added). The PPC eventually settled on a method of "quietly" retrieving the devices. At the PPC meeting on January 10th or 11th, "Chris Harrold [the Director of Compliance] reported that it would be possible to pull shelf devices for testing without a formal recall."

112. Thus, instead of recommending a recall, which would require notification to the FDA, the PPC changed course and "agreed to recommend to OEG that remaining shelf devices should be pulled for testing." The committee "asked the technical team to develop tests to support a recommendation of changed device settings[.]"

113. Had Guidant initiated a formal recall, it would have been required to notify the FDA, and a recall also would have led to communication with the public and health care providers who purchased the devices about the arcing defect. 21 C.F.R. §§ 7.42, 7.46, 7.49, 7.50.

114. The PEC concurred in the PPC's recommendation the next day, January 11, 2005, and agreed to recommend the plan to remove the devices "for testing" to the OEG. The OEG was briefed on this plan on January 13, 2005.

115. On January 12, 2005, Tich sent an email to other members of the PPC, attaching yet another version of a draft physician communication concerning the Renewal. Tich asked his fellow committee members to consider whether the Company should issue a "Product Update," as opposed to a "Safety Alert," because a "Product Update approach would raise less suspicion regarding our motivations, as it appears to be more 'business as usual.' If things get worse and we have to divulge more information, it will not appear in retrospect, as if we were hiding anything."

116. Guidant chose the "business as usual" Product Update approach, issuing such a communication in March 2005. The Update did not mention arcing, the degradation of the polyimide insulation, or the possibility of deaths resulting from the known defect.

117. To the contrary, in the "Q&A" section—which accompanied the Product Update and was sent only to Guidant sales representatives to assist in their communications with physicians—the Update stated that the reason for the communication was a "handful of calls" the Company had received concerning "the appropriate steps to take when a yellow shorted shock lead warning screen appears."

118. The Company emphasized in the Q&A that the Product Update was not a recall or safety alert, but rather a "normal Product Update" and that "Guidant Reliability Assurance publishes Product Updates regularly to ensure that physicians are fully educated on the latest information with regard to the management of our devices." The Q&A expressly represented that "nothing was 'broken.'"

C. The Arcing Defect Is Made Public

119. In March 2005, J.O. died of cardiac arrest after his defective Prizm 2 failed to deliver a potentially life-saving shock due to arcing. J.O.'s physician, Dr. Robert Hauser, learned of the defect in the Prizm 2 when he contacted the Company about his concern regarding the failure of the device to deliver necessary therapy to J.O. On or about May 12, 2005, Dr. Hauser sent an email to various physicians notifying them about J.O.'s death and the defect in the Prizm.

120. Guidant then created a "Prizm 2 Action Plan," in which it decided that it would *not* communicate about the defect to its sales representatives so long as only a limited amount of people outside Guidant knew of the problem. Specifically, in a meeting on May 14, 2005, Guidant decided that it would not initiate a field communication unless:

1) We see a dramatic influx of calls relating to this issue
2) We determine that Medtronic/St. Jude has obtained a photocopy of the Dr. Hauser email
3) We determine that knowledge of this incident has escaped outside of the physicians notified by the Hauser email
4) We receive inquiries on this from the FDA

121. On or about May 19, 2005, the *New York Times* contacted Guidant, informing the Company of its intent to run an article concerning the Prizm defect and the death of J.O.

122. Shortly after learning of the *Times*' intent to publish the article, Guidant contacted the FDA to discuss the possibility of a "Dear Doctor" letter addressing the arcing defect.

123. On May 23, 2005, Guidant issued its first "Dear Doctor" letter informing physicians of the arcing defect in the Prizm devices. It did not mention the cause of the arcing, or that it potentially presented in every device, and said it was a "rare and unpredictable . . . random component failure," even though Guidant knew the cause, mechanism, and predicted rate of failure. The letter made no mention that the Renewal devices also suffered from the arcing defect. In fact, Guidant explicitly stated in a Q&A to its sales representatives accompanying the letter that "[a]ll other Guidant products . . . are not susceptible to this failure mode."

124. On May 24, 2005, the *New York Times* ran a front-page story about J.O.'s death and how Guidant had hidden the defects in the Prizm for years. According to the article, J.O.'s physicians learned that Guidant had been aware of the arcing risk. His physicians

(Drs. Hauser and Barry Maron) also stated that they would have explanted his device had they known about the arcing defect.

125. On June 17, 2005, Guidant issued two "Dear Doctor" letters titled, "URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION." The letters finally disclosed the full extent of the arcing problem with both the Prizm 2 and the Renewal 1 and 2 to physicians.

126. The June 2005 "Dear Doctor" letters stated that the arcing malfunction in these devices "causes damage to the device circuitry, potentially resulting in the inability to deliver the required shock during episodes of arrhythmia." The letters further stated that the "malfunction could lead to a serious, life-threatening event" and that the devices did not provide any warning that they would fail. The Company further acknowledged that it was not possible to estimate the number of devices that might experience such a failure.

127. By the date of the June 2005 Dear Doctor letters, few, if any, defective Prizms and Renewals remained on hospital shelves or in trunk stock because they had already been implanted by physicians in unsuspecting patients or returned to the company.

128. Overall, out of about 16,000 pre-fix Renewals sold that had the potential to arc, there are at least 83 confirmed Renewal arcing events and nine confirmed patient deaths potentially attributable to the Renewal arcing defect.

129. Over 200 devices manufactured before July 28, 2004, the date when Guidant implemented the manufacturing corrective action addressing the known arcing defect in the Renewal, and that had the arcing defect and the attendant potential to fail to deliver a life-

sustaining shock, were implanted by physicians into patients in the United States after July 28, 2004. Approximately 150 of the implants were in Medicare patients.

130. The implantation of Renewal devices with the arcing defect when non-defective devices were available was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

131. The FDA classified the June 17 letters as Class I recalls for those devices.

132. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious adverse health consequences or death. 21 C.F.R. § 7.3(m)(1).

133. The FDA ultimately determined that the Prizm 2 devices that had been manufactured before the April 2002 manufacturing corrective action and the Renewal devices that had been manufactured before the August 26, 2004, stop shipment date were adulterated.

134. Guidant LLC has been convicted of two misdemeanors relating to the arcing investigation. Count One, relating to the Prizm, is under section 331(q)(2) (prohibition on the submission of a report to the FDA that is false or misleading in any material respect) and relates to the August 2003 report that stated that the design change did not affect the safety of the device. Count Two, relating to the Renewal, is under section 331(q)(1)(B) (failure to furnish any notification or other material required under the FDCA) and relates to the March 2005 Product Update, which was a correction that was not properly reported to the FDA.

VII. FALSE CLAIMS

135. As a result of its fraudulent course of conduct, Guidant knowingly caused the submission of false or fraudulent claims for implants of faulty Prizm 2 and Renewal devices to the Medicare program. These false or fraudulent claims were not eligible for payment because the services were not "reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A).

136. A list of claims submitted to Medicare relating to the implant of the faulty Prizm 2 and Renewal devices at issue in this matter has been compiled in an electronic data format that will be served on Guidant contemporaneously with the United States' Complaint In Intervention. The detailed claims information includes (a) the facility at which the implant took place; (b) the patient's name and Medicare ID number; (c) the type of device and date the device was manufactured; (d) the date of the implant; and (e) the amount paid for the services relating to the implant of the device that was paid by Medicare. The claims data has not been filed on the public record in order to protect confidential patient information contained therein.

137. By way of example, listed below are ten example false claims to Medicare for the implantation of the Prizm and Renewal devices into patients, including six false claims for Prizm devices implanted in this District.

Patient	Facility	Date of Service	Device	Medicare Reimbursement
A	Fairview Southdale Hospital (MN)	April 24, 2002	Prizm	$ 30,171.36
B	Florida Hospital Medical Center (FL)	April 25, 2002	Prizm	$ 35,763.43
C	Charleston Area Medical Center (WV)	May 20, 2002	Prizm	$ 35,811.00
D	Abbott Northwestern Hospital (MN)	May 22, 2002	Prizm	$ 20,201.14
E	Methodist Dallas (TX)	June 5, 2002	Prizm	$ 35,756.22
F	Abbott Northwestern Hospital (MN)	June 5, 2002	Prizm	$ 27,048.42
G	United Hospital (MN)	June 7, 2002	Prizm	$ 24,767.64
H	United Hospital (MN)	June 25, 2002	Prizm	$ 32,631.53
I	Abbott Northwestern Hospital (MN)	August 21, 2002	Prizm	$ 24,594.98
J	Western Pennsylvania Hospital (PA)	July 30, 2004	Renewal	$ 44,611.5
K	Providence Hospital (AL)	August 17, 2004	Renewal	$ 25,342.47
L	Winchester Medical Center (VA)	October 14, 2004	Renewal	$ 46,130.20

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

138. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

139. Guidant knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the implantation of defective Prizm 2 and Renewal devices that were not reasonable and necessary and therefore were not reimbursable by the Medicare program.

140. By virtue of the false or fraudulent claims that Guidant caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

SECOND CAUSE OF ACTION

(Unjust Enrichment)

141. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

142. As a consequence of the acts set forth above, Guidant was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States. The United States claims the recovery of all monies by which Guidant has been unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Guidant as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Guidant was unjustly enriched or by which Guidant retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

JOHN R. MARTI
ATTORNEY FOR THE UNITED STATES
Acting under authority conferred by 28 U.S.C. § 515

Dated: January 27, 2011

s/ D. Gerald Wilhelm

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